REMARKS

The presently claimed invention relates to specific androstane compounds, having the general formula as set forth in claim 17, which the inventors have discovered to be useful in the treatment of bacterial infections, particularly in the treatment of gram positive bacterial infections in mammals.

In response to the request in the Office Action, Applicant confirms its telephonic provisional election with traverse to prosecute the invention of Group II, Claims 10-16.

Initially, Applicant requests that the Examiner acknowledge receipt of the Information Disclosure Statement filed on September 24, 2004 prior to issuance of the Office Action to which the present paper responds.

The specification and claims have herein been amended to replace the incorrect structural formula set forth in the application as filed, and other amendments have been made to correct obvious typographical errors and to more clearly define the invention. These amendments do not constitute new matter. The aforementioned amendment to the structural formula corrects an obvious inadvertent typographical error. One of skill in the art, upon review of the specification, would immediately recognize that the structural formula shown prior to the amendment contains a ring system having double bonds therein, when in fact the compounds are clearly described in the text as androstanes, and thus one of skill would understand that the structure originally presented was erroneous, as androstanes do not have double bonds within the ring system. In fact, one of the compounds is specifically named at page 4, lines 11 *et seq.*; one of skill would

recognize that the structure of this compound incorporates the structural formula as revised herein.

The original non-withdrawn claims have been cancelled and rewritten in order to place them in a more logical order that should make it easier for the Examiner to review the claims. Correspondence between the cancelled and new claims is as follows: New claim 17: old claim 10; new claims 18-22: old claim n/a; new claim 23: old claim 15; new claim 24: old claim 16; new claim 25: old claim 13; new claim 26: old claim 14; new claim 27: old claim n/a; new claim 28: old claim 16; new claim 29: old claim 11; new claim 30: old claim 12. To the extent that any subject matter in the new claims does not directly correspond to the old claims, the attention of the Examiner is respectfully directed to the following support in the specification: support for new claim 18 is at page 5, line 18; support for new claim 19 is at page 6, line 1; support for new claim 20 is at page 6, lines 6-7; support for new claim 21 is at page 12, lines 6-7; support for new claim 22 is at page 12, line 9; and support for new claims 23 and 26 is at page 12, lines 16-20.

Claims 10 and 12-15 stand rejected under 35 U.S.C. § 102(b) as anticipated by Lednicer (U.S. Patent No. 3,107,254). The Office Action alleges that these claims recite inventions that are inherently disclosed in Lednicer, and states that the claims are not sufficiently different from the "anticipated prophylactic utility" allegedly set forth in Lednicer. Applicant has carefully considered this rejection, and respectfully traverses for the reasons discussed below.

Lednicer does not disclose or suggest the compounds required by the Applicant's claims. In this regard, Applicant notes that Lednicer's broadest description of his compounds is set forth

in column 1, beginning at line 36. There is clearly an *amino* group at position 17 of all of Lednicer's compounds, whereas Applicant's compounds require an *amido* group at position 17. Thus, Lednicer does not disclose, inherently or otherwise, the same invention as is claimed, as is required for a proper rejection under 102(b). With respect to the *Ex Parte Novitski* citation in the Office Action, it is most respectfully submitted that this case is not applicable.

In summary, accordingly, it is respectfully requested that the rejection of claims 10 and 12-15 under 35 U.S.C. § 102(b) over Lednicer be withdrawn.

Claims 10-15 stand rejected as unpatentable over Nekam (44CA:41152,1950); Lednicer (U.S. Patent No. 3,107,254); Popper (U.S. Patent No. 3,772,283); and Saum (U.S. Patent No. 3,422,094). The Office Action alleges that these references teach various cyclopentanohydrophenanthene compounds as old and well known in combination with pharmaceutical carriers and excipients, and as useful for the treatment of gram positive bacteria. Again, Applicant has carefully considered this rejection, but respectfully traverses it because none of the cited references teach or suggest the compounds required by the presently claimed invention, nor do the references teach or suggest the presently claimed methods of treatment with the compounds required.

It should be noted that Lednicer teaches compositions for oral or parenteral administration (see column 1, lines 22-26), and does <u>not</u> teach topical administration, as is required by Applicant's claims 18 and 19. Applicant has only the Caplus/Chem Abstract printout for Nekam, which does not discuss <u>any</u> methods of administration, nor does Nekam disclose or

suggest the compounds required in the presently claimed methods. The Nekam abstract merely mentions that "androsterone", among other compounds such as Vitamin C, Vitamin K and testosterone, has the ability to "arrest growth" of the fungus *Trichophyton crateriform* and the bacteria *Staphylococcus aureus*.

Similarly, Popper and Saum each fail to disclose the compounds of interest. Popper discloses a series of steroids, more specifically androstadienothizolines, not the steroid amides required by the presently claimed invention. Popper's compounds are quite different structurally from the compounds required by the present invention. Moreover, Popper fails to teach that even its own compounds could be used for administration to mammals to treat bacterial infections. Popper teaches only that some of its compounds could be taken orally as contraceptive agents (see column 4, lines 31-68) or as anti-obesity agents (see column 4, line 69 - column 5, line 11). Popper's only other disclosed ability is employment of the alkyl halide quarternary salts of some of its compounds as cleaner/sterilizers for glassware, surgical instruments, food preparation areas and the like (see column 4, lines 22-30).

Saum discloses steroid cyclic sulfones that are quite different structurally from the compounds required by the present invention. Saum discloses that its compounds have been found to be useful as antibacterial and antifungal agents (see column 2, lines 46-51), but there is no discussion about using these compounds to treat mammals, let alone to topically treat gram positive bacterial infections in mammals.

One of ordinary skill in the art would find no motivation within any of the cited

references, either taken individually or in any combination, to modify the compounds disclosed with these references to achieve the compounds utilized in the present method claims, let alone to use those compounds in the treatment of bacterial infections in mammals. Moreover, there is certainly no motivation for topical administration as is required by some of the claims. In fact, one of ordinary skill in the relevant art understands that minor structural changes of steroids may produce significantly different activity levels and effects. Therefore, it is simply not predictable that all steroids would have an antibacterial effect, nor an effect against gram positive bacteria.

Therefore, it is most respectfully requested that the rejection of claims 10-15 under 35 U.S.C. § 103 over Nekam, Lednicer, Popper and and Saum be withdrawn.

Claim 16 stands rejected under 35 U.S.C. § 103 as unpatentable over Nekam, Lednicer, Popper and Suam, in view of Remington's Pharmaceutical Sciences. The Office Action states that Remington's teaches surface adhering dressings in combination with various antimicrobial compounds, pharmaceutical carriers and excipients. The Office Action acknowledges that claim 16 and Remington differ as to "concomitant employment of the dressing and the therapeutic agent", but concludes that it would be obvious to combine the teachings of the references. This rejection is traversed, because again there is no teaching in the references to combine the compounds required by the present method claims with a dressing. Thus, withdrawal of this rejection is most respectfully requested.

In view of the foregoing, favorable consideration of the claims and allowance thereof is earnestly solicited. The Examiner is invited to telephone Applicant's undersigned representative

if he believes that it would in any way facilitate prosecution of this application.

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Respectfully submitted,

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Louis A. Lofredo, Legal Assistant

4-2-04
Date of Signature